

SECTION 2. 510(k) SUMMARY**MAR 24 2013**

Sponsor/Submitter: Arstasis, Inc.
740 Bay Road

Contact Person: Debra Cogan
Director, Quality Assurance, Regulatory & Clinical Affairs
Phone: (650) 261-8073

Date of Submission: November 21, 2012

Device Trade Name: AXERA 2 Access System

Common Name: Catheter Introducer

Device Classification: Class II

Regulation Number: 21 CFR 870.1340

Classification Name: Catheter Introducer

Product Code: DYB

Predicate Device: AXERA 2 Access System (K123135) manufactured by Arstasis, Inc.; Prelude Sheath Introducer (K070159) manufactured by Merit Medical Systems, Inc.; Pinnacle Introducer Sheath (K984260) manufactured by Terumo Medical Corporation; and Avanti Catheter Sheath Introducer (K945616) manufactured by Cordis Corporation.

Device Description: The AXERA 2 is a device that is comprised of a latchwire, anchor mechanism, shaft and handle with control features.

Indications for Use: The AXERA Access System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. AXERA is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.

Technological Characteristics The AXERA 2 Access Device is designed to create a shallow access path through the arterial wall for the guidewire to enter the vessel lumen.

Performance Data

The AXERA 2 Access Device met all performance testing acceptance criteria.

Summary of Substantial Equivalence:

Modifications to the AXERA 2 Access System consist of changes to the Latchwire, including change to the length of the latchwire, process changes for manufacturing the latchwire, and modifications to the shape of the tip. These design modifications both streamline manufacturing and provide the Physician with the option of using a shorter device to gain arterial access.

There are no changes to the Indications for Use or procedural steps resulting from the changes described within this submission.

Bench testing of the modified AXERA 2 Access System was performed for device specifications affected by the modifications described above, following sterilization of test units. The following tests were performed: device functionality, flex conditioning (Latchwire), Latchwire resistance to flexing, tensile strength of Latchwire to Anchor (parallel and non-parallel), tensile strength of Latchwire distal coil to core wire, and tensile strength of Latchwire proximal coil, latch, and core wire. Simulated use testing was performed on a cadaveric model and confirmed safety of the modified tip shape.

Additional prior bench testing of the AXERA 2 device included accessory functionality, deployment forces (heel, needle, plunger), release forces (heel), flex conditioning (guidewire), tensile strength of multiple joints (anchor, heel, plunger, plunger tube, needle, guidewire, dilator adapter), access needle integrity, compressive strength (handle/anchor, plunger lockout), and torque loading (handle/anchor), corrosion resistance testing, guidewire resistance to fracture, guidewire resistance to flexing, biocompatibility testing, preliminary animal studies (non-GLP) and cadaver assessments, as well as clinical investigations.¹ Multiple clinical evaluations were conducted. The short term safety and clinical performance of the device were established. The long term safety, as well as the ability to access and re-access, was retrospectively studied in a smaller cohort of patients.

In summary, the data provided herein demonstrate that the AXERA 2 Access System is substantially equivalent to its predicate in providing access to the arterial lumen and facilitating the introduction and placement of devices into the peripheral vasculature and promoting hemostasis as an adjunct to manual compression.

¹ The preliminary Animal Studies and Cadaver Assessments were conducted using prototypes of a similar design and configuration.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2013

Arstasis, Inc.
c/o Ms. Debra Cogan
Director, Quality Assurance, Regulatory and Clinical Affairs
740 Bay Road
Redwood City, CA 94063

Re: K123618

Device Name: AXERA 2 Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 12, 2013
Received: February 13, 2013

Dear Ms. Cogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123618

Trade Name: AXERA 2 Access System

Common Name: Catheter Introducer

Indications For Use: The AXERA Access System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. AXERA is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Matthew G. Hillebrenner